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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,658	01/17/2007	Eric Chabriere	0508-1160	8476

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,658	CHABRIERE ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33-35,41 and 42* is/are allowed.

6)☒ Claim(s) *43-54* is/are rejected.

7)☒ Claim(s) *36-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 16-32 have been cancelled and claims 33-54 added as requested in the amendment filed on February 26, 2009. Following the amendment, claims 33-54 are pending in the instant application.

Claims 33-54 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on February 26, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below. New grounds of objection and rejection necessitated by amendment are set forth below as well.

Claim Objections

4. Claims 36-40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 36-40 depend from claim 33, which is limited to a protein, while claims 36-40 encompass nucleic acids. Therefore, claims 36-40 can be infringed by a nucleic acid, which does not infringe claim 33. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe

the basic claim. In the instant case, the nucleic acid claims could be infringed without infringing the claims from which it depends, i.e. the protein claims. Therefore, they are improperly dependent and should be rewritten in independent form.

5. Claims 44, 46 and 49 are not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO: X, wherein "X" is the sequence number. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 43-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 43 and 45 are vague and indefinite for recitation of a variant of the paraoxonase protein. Specifically, it is not obvious if the proteins identified by SEQ ID NO: 4, 5 and 6 are the recited variants or if the claim encompasses the variants of these proteins, such as polypeptides of the structure similar to those paraoxonase proteins of SEQ ID NO: 4, 5 and 6. Applicant is advised that if the variants are the proteins of SEQ ID NO: 4, 5 and 6, then deleting limitation "a variant" from the claim language would obviate this ground of rejection. However, if the recited variants are indeed proteins with a limited structural similarity to the proteins of SEQ ID NO: 4, 5 or 6, then the claims reciting "variants" would be properly rejected under 112, 1, lack of written description.

9. Claims 44 and 46-47 are indefinite for being dependent from indefinite claims.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 48-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record as applied to claims 29-32 in section 23 of Paper mailed on November 26, 2008. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pp. 15-18 of the Response, Applicant traverses the rejection by presenting what appears to be a new set of data, see Figures 1-3, followed by reasoning which strongly implies that it is differential binding of the instant claimed novel protein(s) with PON1 and not with HDL, "the concentration of HPBP in plasma would indicate the risk, in a patient, to develop atherosclerosis". Applicant's arguments have been given careful consideration but not found to be persuasive for reasons that follow.

Section 112 of the patent statute states that in order to satisfy the enablement requirement, an applicant must describe the manner of using the invention "in such full, clear, concise and exact terms as to enable any person skilled in the art … to make and use the same…" 35 U.S.C §112, paragraph 1. Thus, the invention must be enabled at the time of filing and, therefore, the enablement cannot be supported by later obtained experimental results.

Further, *In re Rasmusson* Court held that "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis". *In re Rasmusson v. SmithKline Beecham Corp*. 75 USPQ2D 1297, p1301. See also *In re Brana*, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995), "Enablement, or utility, is determined as of the application filing date."

Thus, based on the evidence of record presented in the instant specification as filed and for reasons of record in the previous office action, the Examiner maintains that the instant claimed methods do not meet the enablement requirement of 112, first paragraph.

With respect to claim 48, which is drawn to methods for determining the concentration of the isolated protein of the instant invention, Applicant is advised that recitation of the use of monoclonal antibodies directed against "different epitopes of the isolated protein" renders the claim not enabled. Although the instant protein of claims 33-35 is novel; however, the "different epitopes" within the entire amino acid sequence of the protein are not shown to be unique. Thus, by broadest reasonable interpretation consistent with the specification, the method of claim 48 would result in determination of concentration of any protein that shares the same six amino acid stretch of an epitope common with the instant protein of SEQ ID NO: 1, and therefore is not enabled for the purpose recited in preamble.

Double Patenting

12. Applicant is advised that should claims 43-44 be found allowable, claims 45-47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, claim 45 encompasses a combination product comprising essentially the same products as claim 43. Because the critical limitations of the two claims are identical, the only distinguishing difference appears to be limited to the intended use recited in claim 45. However, since claim 45 does not specifically add any critical limitations to distinguish the claimed products, recitation of the intended use is not given patentable weight and the scope of the claims appears to be the same. Similarly claims 46-47 are duplicates of claim 44. Recitation of intended use does not distinctly change the claimed compositions currently defined as comprising identical ingredients.

Conclusion

13. Claims 33-35, 41-42 are allowed. Claims 36-40 are objected. Claims 43-54 are rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

April 8, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649